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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/481,572

01/11/2000

JACQUELINE J. SHAN

P8061-9013

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6449

7590

05/19/2006

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WASHINGTON, DC 20005

EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/481,572

**Applicant(s)**

SHAN ET AL.

**Examiner**

Michael V. Meller

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45,47-53 and 55-64 is/are pending in the application.
- 4a) Of the above claim(s) 50,51 and 55-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45,47-49,52,53 and 62-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

The election is maintained for the reasons of record. The election was of ischemic condition and then arrhythmia was examined. No art has been found on ischemic condition or arrhythmia. Thus claims, 50, 51, 55-61 are withdrawn from further consideration since they are non-elected species of diseases.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 47-49, 52, 53, 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating T-type calcium channels in patients having epilepsy, chronic heart failure, congestive heart failure, ischemic conditions, arrhythmia, angina, hypertension, hypoinsulinemia, diabetes, hyperaldosteronemia and preterm labor does not reasonably provide

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enablement for inhibiting T-type calcium channels in any and all patients' cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for a method for a method for treating T-type calcium channels in patients having epilepsy, chronic heart failure, congestive heart failure, ischemic conditions, arrhythmia, angina, hypertension, hypoinsulinemia, diabetes, hyperaldosteronemia and preterm labor , but is not enabled for inhibiting T-type calcium channels in any and all patients' cells.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all types of patients to see if they need their T-type calcium channels inhibited.

Applicant has not shown in their specification any patient who was tested by the claimed method. Applicant has only tested in vitro cells and none of the cells had any of the claimed conditions. Applicant doesn't even have one example which shows that anyone was ever tested with this plant extract for treating any of the claimed conditions. Further, since the claims read on prevention and curing, there is no evidence on the record to show that such diseases were prevented or cured.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

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Applicant's comments are noted but applicant has not limited the invention to diseases/disorders listed above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45, 62, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09227398, see abstract.

JP teaches that diabetes is treated with hypericum perforatum. It is also noted that Dorland's illustrated medical dictionary notes that diabetes when used alone refers to diabetes mellitus, see page 460 of Dorland's.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45, 47-49, 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 09227398 (abstract) taken with Khwaja et al., see col. 20, lines 13-18.

It would have been obvious to adjust the parameters of the amounts of extract being administered to the patient of JP to effectively treat the patient in the best possible way to obtain the best possible results using routine experimentation. JP teaches that diabetes was effectively treated with hypericum perforatum. Thus it is obvious to use a human since diabetes is a common disorder in humans. See also Khwaja who teaches also that this extract can be used to treat diabetes (col. 28, line 2) and col. 11, line 15-25 where it is clear that humans are treated. To extract with methanol or ethanol is common since they are both common solvents used to extract plants and as taught by Khwaja (col. 20, lines 13-18).

Thus it would have been obvious to carry out the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M V Meller', with a long horizontal line extending to the right.

Michael V. Meller  
Primary Examiner  
Art Unit 1655

MVM